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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/403,897	02/22/00	BARKAN	D BARKAN=2

EXAMINER

CANELLA,K

ART UNIT	PAPER NUMBER
1642	19

DATE MAILED: 10/19/01

001444 HM12/1019
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/403,897	Barkan et al
Examiner	**Art Unit**
Karen Canella	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 2-9 and 28-39 is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☒ Claim(s) 35 is/are allowed.

6) ☒ Claim(s) 2-9, 28-34, and 36-39 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

Response to Arguments

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

2. Claims 2-9 and 28-39 are pending and are under consideration.

3. The rejection of claims 2-9 and 28-39 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for inhibiting tumor cell proliferation in vitro , does not reasonably provide enablement for a method of inhibiting tumor cell proliferation in vivo, is withdrawn.

4. The rejection of claims 2-8 and 28, 30-34 and 36-39 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for leptin and leptin fusion proteins, does not reasonably provide enablement for leptin muteins, leptin receptor agonists, or active fragments or thereof as inhibitors of tumor cell proliferation, is maintained for reasons of record. Applicant argues that the Written Description Guidelines allows for variants of a disclosed protein in cases where the variants are contemplated as having the same function and activity of the disclosed protein. This was considered but not found persuasive as the rejections of the instant claims were rejected based on scope of enablement rejections, not written description rejections.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. Claims 2-9, 28 and 29 are rejected under 35 U.S.C. 102(a) as being anticipated by Rubinstein et al (Cytokine, Nov 1997, Vol. 9, No. 11, p. 953, abstract 253). Claims 28 and 2 are

drawn in part to a method for treating tumors or inhibiting tumors in mammals comprising the administration of leptin. Claim 29 specifies the administration of leptin. Claim 3 embodies a growth-factor-dependent tumor. Claims 4 and 5 embody the inhibition or treatment of human breast carcinoma cells. Claim 6 specifies the inhibition of the IRS-1/GRB-2 pathway. Claim 7 is drawn in part to IGF-1. Claim 8 embodies the inhibition of insulin-induced tumor cell proliferation in the treatment of human breast cancer. Claim 9 specifies the active ingredient of leptin. Rubinstein et al discloses a method for treating breast tumors or tumors arising from other tissues comprising the administration of leptin. Rubinstein further discloses that leptin attenuates the insulin-induced tyrosine phosphorylation of the insulin-receptor substrate-1 and that leptin inhibited both the insulin and the IGF-1 dependent proliferation of human ductal carcinoma cells.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Karen A. Canella, Ph.D.
Patent Examiner, Group 1642
October 8, 2001